Complete Summary

GUIDELINE TITLE

Screening for type 2 diabetes mellitus in adults: recommendations and rationale.

BIBLIOGRAPHIC SOURCE(S)

Screening for type 2 diabetes mellitus in adults: recommendations and rationale. Ann Intern Med 2003 Feb 4;138(3):212-4. [3 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Type 2 diabetes mellitus

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for type 2 diabetes in adults and the supporting evidence
- To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, second edition

TARGET POPULATION

- Asymptomatic adults
- Adults with hypertension or hyperlipidemia

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

The following interventions for screening for type 2 diabetes were considered:

1. Fasting plasma glucose (FPG)
2. 2-hour post-load plasma glucose
3. Hemoglobin A1c (HbA1c)
4. Random capillary blood glucose (CBG)

Prevention

Lifestyle interventions, such as exercise, healthy diet, and weight management, for people with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)

MAJOR OUTCOMES CONSIDERED

Key Question No. 1. Is there direct evidence from a randomized controlled trial of screening that screening for diabetes improves health outcomes?

> The four critical health outcomes considered were severe visual impairment, chronic renal failure (i.e., end-stage renal disease), lower extremity amputations, and macrovascular endpoints (cardiovascular disease [CVD] events).

Key Question No. 2. What is the yield of screening, in terms of the accuracy and reliability of screening tests and the prevalence of undiagnosed diabetes in the population?

Key Question No. 3. What is the added efficacy of initiating the treatments below at screening detection rather than at clinical detection in improving health outcomes:

- laser photocoagulation?
- tight glycemic control?
- tight blood pressure control?

- angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs)?
- foot care programs?
- lipid control?

Key Question No. 4. What is the efficacy of lifestyle intervention for people with impaired fasting glucose or impaired glucose tolerance in improving health outcomes?

Key Question No. 5. What are the harms of screening or treatment?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Research Triangle Institute/University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Literature Search Strategy

The analytic framework and key questions guided the literature searches. The Research Triangle Institute examined the critical literature described in the review by the USPSTF (published in 1996) and used their eligibility criteria to develop search terms. They then searched the MEDLINE database and Cochrane library for relevant articles in the English language published between January 1, 1994, and July 30, 2002. They also examined the bibliographies of pertinent articles and contacted experts for other references. When a key question could best be answered by older literature, these studies were also examined.

The search strategy and results are given in Appendix Table 2 in the Review of the Evidence companion document. All searches started with the term "noninsulin dependent diabetes" and other terms were added as appropriate.

Eligibility Criteria for Admissible Evidence

The authors and Task Force liaisons developed eligibility criteria for selecting the evidence relevant to answer the key questions (see Appendix Table 1 in the Review of the Evidence companion document). Key question 1 required a well-conducted randomized controlled trial (RCT) of screening and adequate size and length to estimate health outcomes with reasonable accuracy. Key question 2 required cross sectional or cohort studies in which screening tests were performed on a primary care or general unselected sample and compared with an acceptable

reference standard. For key question 3, they accepted RCTs of treatments with health outcomes that provided information about disease duration and co-morbid conditions in persons with diabetes. For key question 4, they accepted RCTs of people with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) treated with lifestyle or other interventions in which diabetes incidence or development of diabetic complications was an outcome. Key question 5 required RCTs of screened (or treated) versus nonscreened (or nontreated) samples. When such studies could not be found, cohort studies of screening-detected diabetics were examined for evidence of quality of life or psychosocial harms.

NUMBER OF SOURCE DOCUMENTS

Key Question 1: Efficacy of Screening (Direct Evidence) - 0 articles (130 articles were excluded as not meeting inclusion criteria)

Key Question 2: Accuracy and Reliability of Screening Tests: Prevalence of Undiagnosed Diabetes- 7 articles

Key Question 3: Efficacy of Treatment - 28 articles

Key Question 4: Lifestyle Interventions for People with Impaired Fasting Glucose or Impaired Glucose Tolerance - 8 articles

Key Question 5: Harms of Screening or Treatment - 6 articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, or poor).

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Note: See the companion document titled "Current Methods of the U.S. Preventive Services Task Force: a Review of the Process" (Am J Prev Med 2001 Apr;20[3S]:21-35) for a more detailed description of the methods used to assess the quality and strength of the evidence for the three strata at which the evidence was reviewed.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Research Triangle Institute/University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

The Research Triangle Institute's first author and at least one other co-author or trained assistant reviewed all abstracts found in the searches to determine which met eligibility criteria. When either reviewer thought that an abstract might meet criteria, the article was copied for full review. The first author and at least one other co-author or trained assistant reviewed each full article. Those that met eligibility criteria after full review and, when necessary, discussion, were abstracted. Each study was critically appraised using criteria developed by the Methods Work Group of the U.S. Preventive Services Task Force. Articles that met criteria but had methodologically fatal flaws that invalidated the findings were excluded. Abstracted articles that met eligibility criteria and had no fatal flaws were entered into predesigned evidence tables (see Appendix B in the Systematic Evidence Review companion document).

The authors presented an initial work plan and key questions to the Task Force which discussed and made important contributions to the review on several occasions. A draft systematic evidence review was sent for broad peer review. Revisions were made as appropriate after receiving peer review comments.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to 'balance sheets') are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive services affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a 'close-call', then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the

process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, or I), reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians provide [the service] to eligible patients. (The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.)

B

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians provide [the service] to eligible patients. (The USPSTF found at least fair evidence that [the service] improves health outcomes and concludes that benefits outweigh harms.)

C

The U.S. Preventive Services Task Force (USPSTF) makes no recommendation for or against routine provision of [the service]. (The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms it too close to justify a general recommendation.)

D

The U.S. Preventive Services Task Force (USPSTF) recommends against routinely providing [the service] to asymptomatic patients. (The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.)

I

The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. (Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.)

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others. Recommendations for screening for type 2 diabetes in adults from the following groups were discussed: the American Diabetes Association (ADA); the American College of Obstetricians and Gynecologists (ACOG); the American Heart Association (AHA); and the Canadian Task Force on Preventive Health Care (CTFPHC).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening asymptomatic adults for type 2 diabetes, impaired glucose tolerance, or impaired fasting glucose. I recommendation.

The USPSTF found good evidence that available screening tests can accurately detect type 2 diabetes during an early, asymptomatic phase. The USPSTF also found good evidence that intensive glycemic control in patients with clinically detected (not screening detected) diabetes can reduce the progression of microvascular disease. However, the benefits of tight glycemic control on microvascular clinical outcomes take years to become apparent. It has not been demonstrated that beginning diabetes control early as a result of screening provides an incremental benefit compared with initiating treatment after clinical diagnosis. Existing studies have not shown that tight glycemic control significantly

reduces macrovascular complications including myocardial infarction and stroke. The USPSTF found poor evidence to assess possible harms of screening. As a result, the USPSTF could not determine the balance of benefits and harms of routine screening for type 2 diabetes.

The USPSTF recommends screening for type 2 diabetes in adults with hypertension or hyperlipidemia. B recommendation.

The USPSTF found good evidence that, in adults who have hypertension and clinically detected diabetes, lowering blood pressure below conventional target blood pressure values reduces the incidence of cardiovascular events and cardiovascular mortality; this evidence is considered fair when extrapolated to cases of diabetes detected by screening. Among patients with hyperlipidemia, there is good evidence that detecting diabetes substantially improves estimates of individual risk for coronary heart disease, which is an integral part of decisions about lipid-lowering therapy.

Clinical Considerations

- In the absence of evidence of direct benefits of routine screening for type 2 diabetes, the decision to screen individual patients is a matter of clinical judgment. Patients at increased risk for cardiovascular disease may benefit most from screening for type 2 diabetes, since management of cardiovascular risk factors leads to reductions in major cardiovascular events. Clinicians should assist patients in making that choice. In addition, clinicians should be alert to symptoms suggestive of diabetes (ie, polydipsia and polyuria) and test anyone with these symptoms.
- Screening for diabetes in patients with hypertension or hyperlipidemia should be part of an integrated approach to reduce cardiovascular risk. Lower targets for blood pressure (i.e., diastolic blood pressure $\leq$80 mm Hg) are beneficial for patients with diabetes and high blood pressure. The report of the Adult Treatment Panel III of the National Cholesterol Education Program recommends lower targets for low-density lipoprotein cholesterol for patients with diabetes. Attention to other risk factors such as physical inactivity, diet, and overweight, is also important, both to decrease risk for heart disease and to improve glucose control.
- Three tests have been used to screen for diabetes: fasting plasma glucose (FPG), 2-hour post-load plasma glucose (2 hr PG), and hemoglobin A1c (HbA1c). The American Diabetes Association (ADA) has recommended the FPG test ($\geq$126 mg/dL) for screening because it is easier and faster to perform, more convenient and acceptable to patients, and less expensive than other screening tests. The FPG test is more reproducible than the 2-hr PG test, has less intraindividual variation, and has similar predictive value for development of microvascular complications of diabetes. Compared with the FPG test, the 2-hr PG test may lead to more individuals being diagnosed as diabetic. HbA1c is more closely related to FPG than to 2-hr PG, but at the usual cut-points it is less sensitive in detecting lower levels of hyperglycemia. The random capillary blood glucose (CBG) test has been shown to have reasonable sensitivity (75% at a cut-point of $\geq$120 mg/dL) in detecting persons who have either an FPG level $\geq$126 mg/dL or a 2-hr PG level $\geq$200 mg/dL, if results are interpreted according to age and time since last meal;

however, the random blood glucose test is less well standardized for screening for diabetes.

- The ADA recommends confirmation of a diagnosis of diabetes with a repeated FPG test on a separate day, especially for patients with borderline FPG results and patients with normal FPG levels for whom suspicion of diabetes is high. The optimal screening interval is not known. The ADA, on the basis of expert opinion, recommends an interval of every three years but shorter intervals in high-risk persons.
- Regardless of whether the clinician and patient decide to screen for diabetes, patients should be encouraged to exercise, eat a healthy diet, and maintain a healthy weight, choices that may prevent or forestall the development of type 2 diabetes. More aggressive interventions to establish and maintain these behaviors should be considered for patients at increased risk for developing diabetes, such as those who are overweight, have a family history of diabetes, or have a racial or ethnic background associated with an increased risk (eg, American Indians). Intensive programs of lifestyle modification (diet, exercise, and behavior) should also be considered for patients who have impaired fasting glucose or impaired glucose tolerance, since several large trials have demonstrated that these programs can significantly reduce the incidence of diabetes in these patients. Evidence and recommendations regarding counseling about diet, physical activity, and obesity are provided in the USPSTF evidence summaries "Counseling to Promote a Healthy Diet," "Counseling to Promote Physical Activity," and "Screening and Treatment for Obesity in Adults," available on the Agency for Healthcare Research and Quality Web site at www.preventiveservices.ahrq.gov.

Definitions

Recommendation Grades

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms)

A

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve

health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

Strength of Overall Evidence Grades

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor)

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effectiveness of Early Treatment

No trial has been conducted to establish whether systematic screening for diabetes improves health outcomes compared with usual care. Establishing the health benefits of screening for type 2 diabetes is complex because under current practice many patients with diabetes are detected through haphazard screening: about 50% of adults over 45 may have been screened for diabetes in a 3 year period. The U.S. Preventive Services Task Force (USPSTF) attempted to compare the expected health outcomes from a strategy of systematic screening to those from existing care. In the absence of direct evidence from a trial of screening, the USPSTF examined indirect evidence to estimate whether screening, early diagnosis, and treatment of type 2 diabetes were likely to improve four health outcomes compared with usual care/clinical detection: visual impairment, chronic renal failure, lower extremity amputations, and cardiovascular disease (CVD) events.

Additionally, the results from recent randomized controlled trials (RCTs) demonstrate the effectiveness of intensive lifestyle interventions in reducing the incidence of diabetes in individuals with impaired fasting glucose or impaired glucose tolerance. Three large trials in the United States, Finland, and China have demonstrated that intensive programs of lifestyle modification (diet, exercise, and behavior modification) can reduce incidence of diabetes by up to 58% in these patients.

<u>Visual Impairment</u>

The USPSTF concluded that, although retinal photocoagulation is effective in reducing the incidence of visual impairment among those with severe retinopathy or macular edema, most patients detected by routine screening will not require this intervention. Further, although tight glycemic control reduces the development and progression of retinopathy, its effects on serious visual impairment are less clear and probably occur 10 years or more after the diagnosis of diabetes. The degree to which tight glycemic control during the preclinical period between screening and clinical detection (when glucose levels are lower compared with later stages of the disease) reduces retinopathy and later visual impairment is even less certain.

<u>Chronic Renal Failure</u>

The USPSTF concluded that, although tight glycemic and blood pressure control and use of angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) reduce the development and progression of albuminuria, it could not determine whether initiating these treatments earlier as a result of screening would have an important impact on chronic renal failure (CRF).

<u>Lower Extremity Amputations</u>

The USPSTF concluded that lower extremity amputation (LEA) in diabetics occurs primarily as a late complication related to the development of distal sensory neuropathy and peripheral vascular disease, both of which take time to develop. Although foot care programs, and perhaps tight glycemic and blood pressure control, may reduce LEA over the long term, the Task Force found no evidence that early implementation of these interventions during the time between screening and clinical detection would have an impact on the later development of LEA.

Cardiovascular Disease

Four treatments to reduce the incidence of cardiovascular disease (CVD) events among patients with diabetes have been studied in high-quality RCTs: tight glycemic control, tight blood pressure control, treatment of dyslipidemia, and aspirin. No RCT has demonstrated a statistically significant reduction in total CVD events from tight glycemic control. The UK Prospective Diabetes Study (UKPDS) trial (after 10 years of follow-up) showed a trend towards reduced CVD events in patients randomized to tight glycemic control. These patients had lower rates of myocardial infarction (14.7 vs. 17.4 events per 1000 patient-years) and sudden death (0.9 vs. 1.6 events per 1000 patient-years) than those receiving conventional management. Further, there were no reductions in stroke (Relative Risk [RR], 1.11), heart failure (RR, 0.91), angina (RR, 1.02), or all-cause mortality (RR, 0.94).

A number of recent RCTs have examined various aspects of the treatment of hypertension among patients with type 2 diabetes. Principal findings are that an aggressive approach to blood pressure control among patients with diabetes reduces CVD events by a relative 50%; treatment of isolated systolic hypertension among older patients with diabetes reduces CVD events by a relative 34-69%; treatment of those with diabetes and at least 1 other CVD risk factor with ramipril (regardless of whether they have hypertension) reduces CVD events by a relative 22% and all-cause mortality by a relative 16%; and ACE inhibitors and ARBs are useful antihypertensive agents for diabetics.

Several secondary prevention trials of treatments for patients with lipid abnormalities had enough patients with diabetes to permit subgroup analyses. Lipid treatment reduced the incidence of coronary heart disease (CHD) events by about the same relative percentage among those with diabetes as among those without diabetes (relative risk reduction between 19-42%). No primary prevention trial of lipid therapy has included sufficient numbers of patients with diabetes to perform reliable analyses, although trends in these trials are also in the direction of benefit. The Heart Protection Study (HPS) found that including simvastatin in the treatment regimen of diabetic patients reduces major vascular events (myocardial infarction, stroke, and revascularization) from 25% to 20%, i.e. prevents one major vascular event in 20 patients, over a five-year period. Aspirin reduces CHD in both diabetics and nondiabetics, with a comparable relative risk reduction (about 30%) in both groups.

Subgroups Most Likely to Benefit:

Patients at increased risk for cardiovascular disease may benefit most from screening for type 2 diabetes, since management of cardiovascular risk factors leads to reductions in major cardiovascular events.

POTENTIAL HARMS

Potential Harms of Screening and Treatment

Screening for type 2 diabetes could cause harm in several ways. A diagnosis of diabetes could potentially cause "labeling" in asymptomatic individuals (i.e., anxiety or a negative change in self-perception, or both) and could lead to social consequences (e.g., loss of insurability). However, there is little evidence that patients found to have diabetes at screening experience any adverse effect of labeling. Early detection could subject individuals to the potential risks of treatment for longer than if the diagnosis was made clinically, with uncertain benefits. Finally, screening could produce false-positive results, especially since there is not yet complete consensus on criteria for diagnosing diabetes in asymptomatic persons. Further complicating the issue are natural history data that show that between 30-50% of persons labeled as having impaired glucose tolerance or impaired fasting glucose will revert to normal glycemia without developing type 2 diabetes. False-positive screening tests could contribute to psychological distress, a problem known to exist for other conditions.

Treatments for diabetes are relatively safe. Tight glycemic control at a time when glycemic levels are relatively low (i.e., the time between screening and clinical diagnosis) can induce hypoglycemia. In the UK Prospective Diabetes Study, 2.3% of people on insulin suffered a major hypoglycemic episode each year, as did 0.4-0.6% of those on oral hypoglycemic agents. Angiotensin-converting enzyme (ACE) inhibitors and statins have reasonably low levels of serious adverse effects. Finally, although the impact of diabetes treatment on quality of life has been a concern, data from randomized controlled trials indicate that better glycemic control among symptomatic patients improves quality of life, although these findings may not apply to patients detected by screening during the preclinical phase.

The USPSTF concluded that, despite the potential for harm in patients whose diabetes is detected by screening, the magnitude of the problem is unknown. The potential harm for patients is an important consideration because, even if early detection is assumed to be beneficial, several thousand people in the general population may need to be screened to prevent a single diabetes-related complication over a 5-year period. When screening is targeted to patients with hypertension or hyperlipidemia, however, the number needed to screen to prevent a cardiovascular event is substantially lower.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical

recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Neither the resources nor the composition of the U.S. Preventive Services Task Force equip it to address these numerous implementation challenges, but a number of related efforts seek to increase the impact of future U.S. Preventive Services Task Force reports. The U.S. Preventive Services Task Force convened representatives from the various audiences for the Guide "Put Prevention Into Practice. A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach" - clinicians, consumers and policy makers from health plans, national organizations and Congressional staff - about how to modify the content and format of its products to address their needs. With funding from the Robert Wood Johnson Foundation, the U.S. Preventive Services Task Force and Community Guide effort have conducted an audience analysis to further explore implementation needs. The Put Prevention into Practice initiative at the Agency for Healthcare Research and Quality (AHRQ) has developed office tools such as patient booklets, posters, and handheld patient mini-records, and a new implementation guide for state health departments.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the third edition of the Guide to Clinical Preventive Services. Freed from having to serve as primary repository for all of U.S. Preventive Services Task Force work, the next Guide may be much slimmer than the almost 1000 pages of the second edition.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and

altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals and test results are not always centralized.

RELATED QUALITY TOOLS

- Pocket Guide to Good Health for Adults

- A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach

- Screening for Type 2 Diabetes Mellitus in Adults. What's New from the USPSTF.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Screening for type 2 diabetes mellitus in adults: recommendations and rationale. Ann Intern Med 2003 Feb 4;138(3):212-4. [3 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2003 Feb)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a Federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or DHHS agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Alfred O. Berg, MD, MPH, (Chair); Janet D. Allan, PhD, RN, (Vice-chair); Paul Frame, MD; *Charles J. Homer, MD, MPH; Mark S. Johnson, MD, MPH; Jonathan D. Klein, MD, MPH; *Tracy A. Lieu, MD, MPH; C. Tracy Orleans, PhD; *Jeffrey F. Peipert, MD, MPH; *Nola J. Pender, PhD, RN; Albert L. Siu, MD, MSPH; Steven M. Teutsch, MD, MPH; Carolyn Westhoff, MD, MSc; and Steven H. Woolf, MD, MPH

*Member of the Task Force at the time this recommendation was finalized.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

GUIDELINE STATUS

This is the current release of the guideline.

This updates a previously published guideline: U.S. Preventive Services Task Force. Screening for diabetes mellitus. In: Guide to clinical preventive services. 2nd ed; Baltimore (MD): Williams & Wilkins; 1996. p. 193-208.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Also available from the Annals of Internal Medicine Online.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Harris R, Donahue K, Rathore S, Frame P, Woolf S, Lohr KN. Screening adults for type 2 diabetes: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003 Feb 4; 138(3):215-29.

  Electronic copies: Available from the USPSTF Web site and the Annals of Internal Medicine Online.

- Harris R, Lux L, Bunton A, et al. Screening for Type 2 Diabetes Mellitus. Systematic evidence review. Systematic evidence review. Rockville (MD); Agency for Healthcare Research and Quality; 2003 Feb. (Systematic evidence review; No. 25).

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Additional Implementation Tools:

- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2001. 189 p. (Pub. No. APPIP01-0001). Electronic copies available from the AHRQ Web site.

  Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

- The Preventive Services Selector, an application for Palm Pilots and other PDA's, is also available from the AHRQ Web site.
- Screening for type 2 diabetes mellitus in adults. What's New from the USPSTF?. Rockville (MD): Agency for Healthcare Research and Quality; 2003 Feb. Electronic copies: Available from USPSTF Web site.

PATIENT RESOURCES

The following is available:

- The Pocket Guide to Good Health for Adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on January 31, 2003.

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